

UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Robert Kopesky et al.

: Group Art Unit: 1609

Application No.: 10/521,886

: Examiner: Layla D. Bland

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For: Production of Microcrystalline Cellulose

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Sir:

REPLY BRIEF

This is a Reply Brief in an appeal from the rejections set forth in the Final Rejection dated October 30, 2007, (hereinafter “the Final Rejection”) in the above-identified application. Appellant respectfully submits that the rejections in the Final Rejection which were not withdrawn in the Examiner’s Answer dated August 4, 2008, were made in error, and that the rejections should be reversed for the reasons set forth in the Appeal Brief filed on May 30, 2008, as supplemented by the reasons set forth herein. This brief is being filed to address errors and new issues raised by the Examiner in the Examiner’s Answer.

The applicant will not request an oral hearing in this appeal and thus a decision based on the written record is requested.

The present Reply Brief is filed to ensure that certain errors made by the Examiner in the Examiner’s Answer are fully briefed and corrected. In addition, the present Reply Brief addresses some new positions taken by the Examiner for the first time in the Examiner’s Answer. The arguments made herein are intended to supplement the previously filed Appeal Brief and not to repeat the arguments made therein. Thus, for applicant’s complete argument, reference should be had to both the Appeal Brief and this Reply Brief.

In the Examiner’s Answer on page 8, the Examiner takes the position that, “Schaible teaches a process wherein cellulose is hydrolyzed by active oxygen.” However, the

depolymerization reaction in Schaible is hydrolysis of the cellulose by acid and not by active oxygen. Schaible nowhere indicates that active oxygen hydrolyzes cellulose nor does Schaible teach that active oxygen depolymerizes the cellulose. Rather, it is clear that the active oxygen of the Schaible process bleaches the cellulose. This is confirmed by the fact that Example 16 of Schaible, which did not employ active oxygen still resulted in depolymerization of the cellulose. Also, Schaible indicates that the advantage of adding active oxygen to an acid hydrolysis process is that it eliminates the need to perform multiple steps to accomplish both hydrolysis and bleaching. Further, the examples of Schaible show that the active oxygen causes bleaching of the cellulose (see e.g. Example 1 of Schaible). From this it is clear that the active oxygen of Schaible is used for bleaching and that there is no evidence that the active oxygen of Schaible participates in the hydrolysis reaction as the Examiner alleges. Thus, the Examiner erroneously concludes that the active oxygen of Schaible, rather than the acid, causes hydrolysis.

The Examiner also concludes on page 7 of the Examiner's Answer that, "Trusovs uses alkaline conditions along with hydrogen peroxide to depolymerize (or hydrolyze) and reduce the viscosity of the cellulose suspension [column 2, lines 54-64]." However, again there is no basis in Trusovs or elsewhere in the record to conclude that active oxygen depolymerizes cellulose by hydrolysis as the Examiner now suggests. Specifically, referring to column 2, lines 54-64 of Trusovs relied on by the Examiner in support of her position, there is no reference to hydrolysis. In fact, neither Schaible nor Trusovs indicates that active oxygen hydrolyzes cellulose. Rather, what Trusovs actually teaches is that peroxides oxidize and depolymerize cellulose (see col. 2, lines 51-53 of Trusovs). The Examiner speculates that the depolymerization of Trusovs involves hydrolysis when, in fact, there is no evidence in the record to demonstrate that hydrolysis actually occurs in the reaction disclosed in Trusovs.

In addition, evidence in the present specification suggests that the depolymerization reaction of Trusovs involves oxidation, as mentioned at col. 2, lines 51-53 of Trusovs, since: (1) depolymerization with active oxygen occurs independent of whether acid is present or absent to perform hydrolysis, and (2) with certain cellulosic materials the degree of polymerization achieved using active oxygen is lower than could previously be achieved using acid hydrolysis processes indicating that active oxygen depolymerizes by a different reaction mechanism than

occurs in acid hydrolysis (see page 9, lines 10-16 of the present application). The Examiner has neglected to address this evidence in the Examiner's Answer and thus for this additional reason, the Examiner's conclusion that the mechanism of the Trusovs depolymerization is hydrolysis, should be disregarded as both unsupported by evidence and contradicted by the present specification and Trusovs itself.

The foregoing point is important since, as explained in detail in the Appeal Brief, a skilled person would not consider the Trusovs method interchangeable with the methods of Schaible and Hanna since the evidence of record indicates that the mechanism and products of the depolymerization reaction of Trusovs employing active oxygen are significantly different from the mechanism and products of the acid hydrolysis depolymerization reaction of Schaible and Hanna. A skilled chemist would therefore not predict that steps taken in the depolymerization reaction of Trusovs would have the same effect if employed in the depolymerization reactions of Schaible and Hanna since a skilled person is well aware that small changes in chemical reactions may produce significantly different results.

The Examiner further alleges at page 8 of the Examiner's Answer that, "Hanna teaches that extrusion conditions allow more intimate contact between cellulose and the depolymerization reagent, resulting in shorter reaction time and less reagent required." This is not a correct characterization of the Hanna teaching. Rather, Hanna teaches that the extrusion conditions cause melting of the cellulose (see col. 4, lines 12-15 of Hanna). Hanna then states that melting of the cellulose allows more intimate contact between the cellulose and the acid (see col. 4, lines 15-16).

Based on the Examiner's erroneous characterization of the Hanna teaching, the Examiner reaches the incorrect conclusion at page 8 of the Examiner's Answer that, "The skilled person would expect that regardless of which reagent was used for depolymerization, the 'more intimate contact' taught by Hanna's extrusion conditions would exist, and thus the skilled artisan could reasonably expect shorter reaction time." The Examiner has missed the point of Hanna that melting of the cellulose is what gives the more intimate contact. A skilled person would only expect a shorter reaction time due to more intimate contact of reactants if the skilled person were comparing the process of Hanna wherein the cellulose is melted to a process wherein the cellulose is not melted. The problem with the Examiner's analysis is that the Examiner nowhere

demonstrates that the processes of Schaible and Trusovs do not melt the cellulose. As a result, without knowing this key fact, the skilled person is not in a position to conclude that more intimate contact of reactants and the resultant shorter reaction time would be achieved using the process of Hanna. Rather, if the processes of Schaible or Trusovs do, in fact, melt the cellulose, the skilled person would conclude that no advantage would be achieved by the process of Hanna since Hanna clearly teaches, as discussed above, that the more intimate contact results from melting of the cellulose. Accordingly, the Examiner's rationale that more intimate contact of the reagents would be expected by using the Hanna process is not supported by the record since the record does not support a conclusion that the cellulose of the processes of Schaible or Hanna is not melted.

In fact, Hanna teaches that extrusion may be carried out at an extruder barrel temperature as low as 80°C (col. 3, line 63 of Hanna), whereas both Schaible and Trusovs contemplate operation of their processes at temperatures up to about 100°C (p. 7, line 20 "boiling temperatures" and Examples of Schaible and col. 2, line 56 of Trusovs). Further, Schaible contemplates operation of its process at high pressure (see p. 7, lines 20-21 of Schaible) and Trusovs contemplates operation of its process with mixing (see col. 3, lines 12-17 of Trusovs). From these facts, the skilled person would not be able to conclude that the processes of Schaible and Trusovs do not melt the cellulose since the important reaction conditions of Schaible and Trusovs appear to overlap with the reaction conditions of Hanna. Accordingly, the skilled person would not have any basis for concluding that the use of the extruder in Hanna would necessarily reduce the reaction time of the Schaible or Trusovs processes since the evidence does not demonstrate that the melting of the cellulose in Hanna is not also occurring in the processes of Schaible and Trusovs.

On page 9 of the Examiner's Answer, the Examiner offers a new second alleged motivation for combining the processes of Hanna, Schaible and Trusovs, namely, that, "...each of the references is drawn to production of microcrystalline cellulose using acidic conditions or alkaline conditions, active oxygen, or combinations of the same, and combining them is reasonable." This conclusion is riddled with errors. First, Trusovs does not produce microcrystalline under acidic conditions. Second, Hanna does not produce microcrystalline

cellulose under alkaline conditions. Third, Schaible does not produce microcrystalline cellulose under alkaline conditions. Fourth, Hanna does not use active oxygen to produce microcrystalline cellulose.

In addition, the Examiner is required to specifically set forth the motivation for a skilled person to combine the references. A mere conclusory statement that the references relate to the production of microcrystalline cellulose is insufficient to meet the Examiner's burden of proof on this issue. "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co. v. Teleflex Inc.*, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

Finally, as discussed in greater detail in the Appeal Brief, there are several reasons why the skilled person would not combine these references including at least that: (1) the reaction mechanisms and products of the reactions are different, (2) Trusovs is specifically directed to avoiding use of acid hydrolysis to overcome its attendant disadvantages, whereas both Hanna and Schaible employ acid hydrolysis, and (3) there is no predictable advantage of the combination of references proposed by the Examiner. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___ , 82 USPQ2d 1385, 1396 (2007).

At page 9 of the Examiner's Answer, the Examiner dismisses the applicant's argument that the present invention is unobvious because it provides the significant, unexpected benefit that microcrystalline cellulose with a lower degree of polymerization can be obtained than via a conventional acid hydrolysis process. The Examiner reasons that since claim 1 does not require a particular degree of polymerization, that this advantage of the present invention can be ignored. This is legal error since this advantage of the invention presented in the specification must be considered. See, e.g., *Soni*, 54 F.3d at 750, 34 USPQ2d at 1687 (error not to consider evidence presented in the specification). Moreover, this advantage results from the claimed method of using high shear in combination with active oxygen to accomplish depolymerization as described

in the specification (see Example 2 on pages 13-14 where the degree of polymerization achieved by the active oxygen method of the present invention (samples 1-5) is consistently lower than the degree of polymerization achieved by comparable acid hydrolysis methods (samples 6-9). This evidence cannot be disregarded merely because the claim does not recite a degree of depolymerization. Rather, this evidence must be given substantial weight since the applicant has clearly demonstrated a nexus between the claimed invention, i.e. use of active oxygen and an extruder, and the advantageous results. This is a significant, unexpected advantage since it allows production of alternative microcrystalline cellulose products with different properties and the Examiner has not demonstrated that the prior art renders this advantage predictable. Accordingly, this advantage must be considered and clearly supports the non-obviousness of the present invention.

On page 9 of the Examiner's Answer, the Examiner again mischaracterizes the teachings of Hanna when the Examiner states that, "Hanna teaches that harsh hydrolysis conditions, such as higher temperatures and higher acid concentrations, along with the speed of the extruder screw, increase hydrolysis..." The portion of Hanna relied on by the Examiner in support of this statement, namely, col. 5, lines 54-64 of Hanna, nowhere states that harsh hydrolysis conditions or the speed of the extruder screw increase hydrolysis. The amount of hydrolysis is measured by Hanna in terms of the level-off degree of polymerization (LODP) (see col. 1, lines 19-23 of Hanna) and not in terms of the particle size of the microcrystalline cellulose which is discussed at col. 5, lines 54-64 of Hanna relied on by the Examiner.

Further, Hanna teaches that the particle size and LODP are primarily determined by selection of the starting cellulose material and not by the hydrolysis conditions. For example, Hanna states that, "...the size of the microcrystalline cellulose particles obtained through this process depends mostly on the source of the cellulose used..." (Col. 5, lines 53-55 of Hanna). Also, Hanna indicates the measured LODP of wood-cellulose microcrystalline cellulose is 220 whereas the LODP of the cellulose in rayon tire cord microcrystals is only about 30 (col. 5, line 67 to col. 6, line 3 of Hanna). Notable is that no range of LODP is given to account for use of harsher hydrolysis conditions. Rather, for a particular starting material, there is a particular LODP. This indicates that the LODP, the measure of the degree of hydrolysis, is primarily

dependent on the source of the starting material. Thus, there is no basis in Hanna for the Examiner's conclusion on page 10 of the Examiner's Answer that the achievement of a lower degree of polymerization under extrusion conditions would be expected. Rather, the appropriate conclusion to draw from col. 5, lines 54-64 of Hanna is that microcrystalline cellulose having particle sizes below 200 microns can be produced using harsh hydrolysis conditions and/or a higher extruder screw speed.

On pages 10-11 of the Examiner's Answer, the Examiner for the first time offers a specific rationale as to why the features of claim 14 are allegedly taught or suggested by Schaible, relying on Example 7 of Schaible. However, there are several errors in the Examiner's rationale.

Claim 14 requires that: (1) the extrusion system comprises a twin screw extruder, (2) the cellulose material comprises about 30% to about 50% by weight of the reaction mixture, and (3) the active oxygen compound used in the depolymerization reaction is hydrogen peroxide and comprises about 0.1% to about 10% by weight of the reaction mixture, on a 100% active basis of hydrogen peroxide.

First, Schaible uses 40 g of cellulose material in 3 liters of solution and not one liter of solution as the Examiner indicates (see page 8, lines 2-4 of Schaible). Second, use of 40 g of cellulose material in 3 liters of aqueous solution (density of about 1 g/ml or 1000 g/liter), with 10 g of Oxzone added, results in a weight percentage of cellulose material of $(40/3010) * 100 =$ about 1.3%. Thus, the limitation of claim 14 requiring that the cellulose material comprise about 30% to about 50% by weight of the reaction mixture is not taught by Schaible.

Third, the calculation of 10% of hydrogen peroxide used in Example 7 of Schaible is incorrect since Schaible reacts the hydrogen peroxide with an excess of sulfuric acid to form a peroxy acid prior to addition of the cellulose material. Thus, there is no hydrogen peroxide used in the depolymerization step of Example 7 of Schaible since all of the hydrogen peroxide has been converted to peroxy acid prior to mixing with the cellulose material. Thus, since no hydrogen peroxide is mixed with the cellulose in the Schaible process, Schaible also fails to teach the limitation of claim 14 which requires that the active oxygen compound used in the

depolymerization reaction is hydrogen peroxide and comprises about 0.1% to about 10% by weight of the reaction mixture, on a 100% active basis of hydrogen peroxide.

Thus, the Examiner's reasoning in relation to claim 14 is incorrect and should be disregarded.

The Examiner again mischaracterizes the teachings of Hanna at the top of page 11 of the Examiner's Answer stating that, "Hanna teaches that the ratio of acid solution to cellulose under conventional conditions is between 5:1 to 8:1, compared to 1:1 under extrusion conditions." What Hanna actually teaches is that conventional batch-type acid hydrolysis processes that require excess water and acid have acid solution to cellulose ratios of 5:1 to 8:1 (see col. 4, lines 16-22 of Hanna). The important point to note is that Hanna expressly qualifies this teaching by referring to a specific subclass of conventional processes, namely, "batch-type acid hydrolysis processes that require excess water and acid." Thus, unless a skilled person starts from a conventional batch-type acid hydrolysis process that requires excess water and acid, there would be no expectation from the teachings of Hanna that there would be a benefit to the use of extrusion.

Further, the lower acid requirement referenced by Hanna which allows the use of the 1:1 acid/cellulose ratio is said to be possible because of the more intimate contact between the cellulose and the acid which results from the melting of the cellulose in the method of Hanna (see col. 4, lines 12-20 of Hanna).

Trusovs does not relate to a conventional batch-type acid hydrolysis process since Trusovs does not employ acid or acid hydrolysis. Thus, the skilled person cannot predict the effect of extrusion on the amount of depolymerization agent that will be required in Trusovs from the teachings of Hanna since Hanna only compares its reaction to a conventional batch-type acid hydrolysis process and not to a process such as is disclosed in Trusovs.

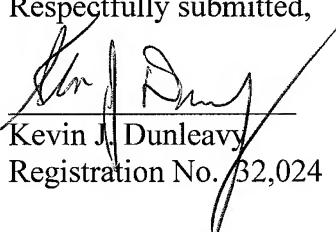
Further, as discussed above, the Examiner has not demonstrated that the methods of Trusovs and Schaible do not melt the cellulose and thus already provide the more intimate contact among the reagents that allows a reduction in the amount of depolymerization reagent touted by Hanna. In fact, as discussed above, the overlap in the reaction conditions used in Hanna, Schaible and Trusovs appear to contradict a conclusion that there is no melting of the

cellulose in the Schaible and Trusovs processes, thereby negating the alleged advantage of Hanna. Accordingly, the Examiner's reasoning is not consistent with the evidence and should be disregarded.

Finally, on page 11 of the Examiner's Answer, the Examiner presents an alleged basis for the limitations of claims 15-16 in a combination of Hanna and Schaible. Neither Schaible nor Hanna teach residence times in the reactor or extruder of 15 minutes or less, as claimed in claims 15-16. Schaible teaches a residence time of 2 hours in the reactor. The Examiner again attempts to rely on the teaching of Hanna that reaction times can be reduced compared to conventional batch-type acid hydrolysis reactions due to melting of the cellulose material to conclude that Hanna provides the expectation of a shorter reaction time if an extruder were used in the process of Schaible. As discussed above, this would only be persuasive if the Examiner demonstrated that the Schaible process is a process in which no melting of the cellulose takes place. Since this underlying fact has not been proven, the Examiner's conclusion again fails for the same reasons as given above.

For the foregoing reasons, and the reasons set forth in the Appeal Brief dated May 30, 2008, Appellant respectfully submits that each of the remaining outstanding rejections should be reversed, and that the pending claims should be allowed. Such a decision is respectfully solicited.

Respectfully submitted,


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